

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jun 2026

### fibrinogen and blood requirement in trauma patients

#### Protocol summary

##### Summary

Uncontrollable and excessive blood loss is one of the inevitable elements of the mismanagement in trauma patients. In acute blood loss, fibrinogen amount decreases which in turns increases bleeding. Fibrinogen concentrate allows rapid access to fibrinogen supplementation in smaller volumes. In this randomized, double blinded and single center study, the primary outcome was comparing the effect of prophylactic fibrinogen supplementation on transfusion requirement in trauma patients. Inclusion criteria: All trauma patients. Exclusion criteria: Patients having received fibrinogen or cryoprecipitate before operation, Patients with hereditary or acquired coagulopathies and history of allergy to fibrinogen concentrate. After anesthesia induction and intubation and before the start of the surgery, patients in the control group will receive 30 mg/kg of fibrinogen concentrate (diluted in 100 mL of distilled water) within 10 minutes. Transfusion requirement in patients, determining and comparing the complications from fibrinogen concentrate and hemoglobin levels before and after surgery will be compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016050220795N3**

Registration date: **2016-05-15, 1395/02/26**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-05-15, 1395/02/26

##### Registrant information

###### Name

Samad Golzari

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 3556 6183

###### Email address

golzaris@tbzmed.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Investigator

###### Expected recruitment start date

2016-05-21, 1395/03/01

###### Expected recruitment end date

2016-06-21, 1395/04/01

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

fibrinogen and blood requirement in trauma patients

###### Public title

Effect of prophylactic fibrinogen on the need for perioperative blood transfusion in traumatic patients undergoing abdominal surgery

###### Purpose

Prevention

###### Inclusion/Exclusion criteria

Inclusion criteria: All trauma patients. Exclusion criteria: Patients having received fibrinogen or cryoprecipitate before operation, Patients with hereditary or acquired coagulopathies and history of allergy to fibrinogen concentrate.

###### Age

No age limit

###### Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 40

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

##### Street address

Tabriz University of Medical Sciences, Golgasht St., Tabriz

##### City

Tabriz

##### Postal code

#### Approval date

2010-09-23, 1389/07/01

#### Ethics committee reference number

TBZMED.REC.1395.24

## Health conditions studied

### 1

#### Description of health condition studied

Injury of intra-abdominal organs

#### ICD-10 code

S36

#### ICD-10 code description

Injury of intra-abdominal organs

## Primary outcomes

### 1

#### Description

Transfusion requirements

#### Timepoint

Before and after surgery

#### Method of measurement

Hemoglobin levels

## Secondary outcomes

### 1

#### Description

fibrinogen plasma level

#### Timepoint

Before and after surgery

#### Method of measurement

fibrinogen plasma level

## Intervention groups

### 1

#### Description

Ppatients in the control group will receive 30 mg/kg of fibrinogen concentrate (diluted in 100 mL of distilled water) within 10 minutes.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: No intervention will be made in this group.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Reza Hospital

##### Full name of responsible person

Samad Eslam Jamal Golzari

##### Street address

Imam Reza Hospital, Golgasht St., Tabriz

##### City

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Samad Eslam Jamal Golzari

##### Street address

Imam Reza Hospital, Golgasht St., Tabriz

##### City

Tabriz

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

**Title of funding source**

Tabriz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector***empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Samad Eslam Jamal Golzari

**Position**

Assistant Professor

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*